

Julie A. Socha
Bryn Mawr College
C-786
Bryn Mawr, PA 19010
(610) 526-7653

April 13, 2001

Docket Management Merion Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir or Madam,

I'm writing to the Food and Drug Administration in reference to a proposed rule that was recently published in the Federal Register on March 23, 2001, "00N-1269 Labeling for Human Prescription Drug/Biologic Products". While browsing through the register I noticed this rule particularly because of its direct relevance to the public. The clarity of labeling on medical prescriptions is of the utmost importance in America in order to properly administer medicine to citizens.

Although I do not know a great deal about the current format and standards for prescription drug labeling, I would assume that any logical adjustment to the layout of information on prescriptions would be helpful to the medical field. Therefore, I believe this aspect of the newly proposed rule ought to become part of a future final rule because it is in the best interests of the patients.

In the proposal the administration states the following:

"The proposal would also amend prescription drug labeling requirements for older drugs to require that certain types of statements currently appearing in labeling be removed if they are not sufficiently supported."

This part of the proposed rule seems extremely broad. Exactly what "types of statements" are the rule makers referring to? Also how would one go about deciphering between what "types of statements" are "not sufficiently supported" and what ones are? I realize that it is difficult for agencies to create specific rules and still cover a wide scope of situations. However, perhaps in the Food and Drug Administration's final rule it would be more productive if the segment that is quoted above were to be restated for the purpose of additional clarity.

Thank you very much for your time and attention to this matter. I hope my comments have been useful.

Sincerely,

Julie A. Socha
Julie A. Socha

00N-1269

C35

2046

01 MAY

MD 56

Julie A. Socha
Bryn Mawr College
C-786
101 N. Merion Ave.
Bryn Mawr, PA 19010



Docket Management Merion Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

20857+0001

